Summary of Safety and Effectiveness for ^{125}I Brachytherapy SnapSeeds

SEP 1 9 2000

K001366

submitted by
Prostec LLC
8200 NW 27 Street
Miami, Fl 33122
Phone: (305) 716-7000
Facsimile: (305) 716-7020

Identification of Device

Classification Name:	Radionuclide brachytherapy source
Common/Usual Name:	^{125}I Radioactive Seeds
Proprietary Name:	Prostec ^{125}I Brachytherapy SnapSeed
Classification:	Class II, classification number is 90KXK

Identification of a Legally Marketed Predicate Device

The brachytherapy seed portion of this device is identical to the Prostec LLC ^{125}I Brachytherapy Seed cleared by 510(k) Number K993280. The addition of the resorbable spacers to this device make it substantially equivalent to the Amersham/Medi+Physics Model 7000 seeds, which are legally manufactured and distributed pursuant to 510(k) K940632.

Device Description

The ^{125}I Brachytherapy SnapSeeds consist of ^{125}I absorbed onto the surface of a spherical polymeric substrate sealed in a welded titanium casing. The SnapSeeds are assembled into a chain containing 2 to 10 SnapSeeds placed on 1 cm centers. The center-to-center spacing is maintained by resorbable polydioxanone suture material.

Typically, the ^{125}I Brachytherapy SnapSeeds are placed within or in close to the tumor to be treated utilizing guidance. The devices are delivered using an 18 gauge thin wall or greater diameter hypodermic needle.

Intended Use

^{125}I Brachytherapy SnapSeeds are intended for permanent interstitial implantation in selected localized tumors. The devices are implanted as a source of nuclear radiation for therapy.

Summary of Technological Characteristics

The table below compares the technological characteristics of the ^{125}I Brachytherapy SnapSeeds to the predicate device.

Feature	^{125}I Brachytherapy SnapSeeds	Predicate Device
Manufacturer	Prostec LLC	Amersham/Medi+Physics
510(k) Number	K993280	K940632
Sterilization Method	Ethylene Oxide Gas	Ethylene Oxide Gas
Intended use	^{125}I Brachytherapy SnapSeeds are intended for permanent interstitial implantation in selected localized tumors. The devices are implanted as a source of nuclear radiation for therapy.	I-125 RAPID™ Strands are indicated for permanent interstitial implantation of selected localized tumors which are of low to moderate radiosensitivity. They are to be used as primary treatment (such as prostate cancer or unresectable tumors) or residual disease after excision of the primary tumor. I-125 RAPID Strands™ may be indicated for use concurrent with or at the completion of other treatment modalities, such as external beam radiation or chemotherapy.
Capsule	Titanium	Titanium
Capsule Sealing Method	Laser Weld	Weld
Radioisotope	^{125}I	^{125}I
Half-life	59.4 days	59.4 days
Principal Energy Levels (keV)	27.4, 31.4, and 35.5	27.4, 31.4, and 35.5
Radiographic Marker	Yes	No
Packaging	Stainless steel tube in a sealed plastic tray placed in a DOT shipping carton	Stainless steel tube in a sealed plastic tray placed in a DOT shipping carton
Seed Length	4.5 mm	4.5 mm

Feature	^{125}I Brachytherapy SnapSeeds	Predicate Device
Outside Diameter	0.8 mm	0.8 mm
Center-to-Center Seed Spacing	1.0 cm	1.0 cm
Application Method	Through an 18 thin wall gauge hypodermic needle	Through an 18 gauge thin wall hypodermic needle
Spacer Material	Resorbable suture material	Resorbable suture material
Apparent Activity Level (per seed)	0.1 to 5.0 mCi	0.18 to 1. 0 mCi
Point-source approximation anisotropy constant $\bar{\phi}_{an}$	0.96	0.95
Dose rate Constant *cGy/hr/U*, 1999 NIST	1.05	1.04
Seed Strength Specification	Apparent activity in mCi and air-kerma	Apparent activity in mCi and air-kerma
Residual Activity	< 0.2 μCi after 2 years	< 0.2 μCi after 2 years

Summary of Performance Data

The ^{125}I Brachytherapy SnapSeeds comply with the following standards, practices, and guidances:

- ISO 2919-1980(e), *Sealed radioactive sources — Classification*, International Organization for Standardization, First Edition (1980)
- ISO/TR 4826-1979(E), Technical Report 4826: *Sealed radioactive sources — Leak test methods*, pg 2 , International Organization for Standardization (1979)

The tissue contact materials of the ^{125}I Brachytherapy SnapSeeds meet the requirements of the following recognized consensus standards.

- ASTM F 1472 – 93, Standard Specification for Wrought Ti-6Al-4V Alloy for Surgical Implant Applications.
- ASTM F 67 – 95, Standard Specification for Unalloyed Titanium for Surgical Implant Applications.

The tissue contact material of the ^{125}I Brachytherapy SnapSeeds spacer is made from a legally marketed suture.

Brachytherapy is an old and well-established medical treatment. ^{125}I is a well-characterized radioactive source for brachytherapy treatment. The use of ^{125}I is has been documented by B. C. Hilaris, D. J. Holt and J. St. Germain in FDA Report 76-8022.†

Since the ^{125}I Brachytherapy SnapSeeds meet the requirements of the stated standards and embody technological characteristics essentially identical to the predicate device, we believe the device is safe and effective and performs as well as or better than the predicate device. The ^{125}I Brachytherapy SnapSeeds will be manufactured per specifications and good manufacturing practices that ensure the device is safe and effective for its intended use.

† Hilaris BC, Holt DJ, St. Germain J: *Use of Iodine ^{125}I Radioactive Seeds for Interstitial Implant*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 9 2000

Al Weisenborn
Prostec LLC
19526 East Lake Drive
Miami, FL 33015

Re: K001366
Prostec I-125 Brachytherapy Snapseed
Dated: August 9, 2000
Received: August 14, 2000
Regulatory class: II
21 CFR 892.5730/Procode: 90 KXK

Dear Mr. Weisenborn:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Indications for Use

510(k) Number (if known): K001366

Device Name ^{125}I Brachytherapy SnapSeeds

Indications for Use:

^{125}I Brachytherapy SnapSeeds with integral spacers are intended for permanent interstitial implantation in selected localized tumors. The devices are implanted as a source of nuclear radiation for therapy.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001366